a4 cancelled

room temperature.

a5

50. (Once Amended). The solid oral dosage form according to claim 49, wherein the capsule is coated with a rate controlling polymer.

Please add Claim 52 as follows.

a6

--52. (New Claim). A dry-blended composition in solid oral dosage form and comprising a drug and, as an enhancer, a salt of a medium-chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.--

REMARKS

Reconsideration of the patentability of applicants' claims is requested respectfully.

Status of the Claims

The Examiner's Action addresses all of applicants' pending claims namely Claims 1 to 51. Claims 1, 4, 39, 41, 47, and 50 have been amended. Claims 2, 40, 43 to 46, and 48 have been cancelled. Claim 52 has been added. Accordingly, there is presented for the Examiner's consideration Claims 1, 3 to 39, 41, 42, 47, and 49 to 51.

Summary of Examiner's Rejections

Claim 40 has been rejected as indefinite under 35 U.S.C. § 112 and an improper recitation of use under 35 U.S.C. § 101.

Claims 1 to 13, 15 to 39, and 41 to 51 have been rejected under 35 U.S.C. § 102(b) as being anticipated by the disclosure is WO 97/05903 to Watts *et al.*(hereafter *"Watts et al."*)

Claims 1 to 14 and 41 to 51 have been rejected under 35 U.S.C. § 103(a) as being obvious to one of ordinary skill in the art in view of the disclosure of the aforementioned Watts et al. reference.

Reconsideration of the Examiner's rejections is requested respectfully.

Discussion of the §112 Rejection

Claim 40 has been cancelled, thus rendering the Examiner's § 112 and § 101

rejections moot.

Summary of Applicants' Claimed Invention

Independent Claims 1 and 47 have been amended and Claim 52 has been added to define applicants' composition as one which is a solid at room temperature and which is prepared from constituents, all of which are solids at room temperature. Applicants' composition comprises a drug and, as a drug enhancer, a solid fatty acid salt or a solid salt of a derivative of a fatty acid of the type defined in the claims. Other of applicants' method of treatment claims (Claim 39) and method of preparation claims(Claim 41) have been amended to recite also the "solid" characteristics of applicants' composition.

It is believed that the amended claims define patentably over the cited art, as discussed below.

Discussion of the Examiner's Rejections

The Examiner's § 102(b) rejection is traversed respectfully. The Watts et al. reference discloses compositions which are liquid or semi-solids (page 8, line 21). The reference discloses further that at least one absorption-enhancing component of the composition comprises a liquid or semi-solid dispersant (page 9, lines 8-12). The Watts et al. reference does not disclose a solid composition nor a composition prepared from constituents, all of which are solids at room temperature. Accordingly, the Watts et al reference does not anticipate applicants' claims.

Withdrawal of the Examiner's § 102 rejection is requested respectfully.

The Examiner's § 103 rejection is traversed also. As discussed above, applicants' claims define a composition which includes a solid fatty acid salt or solid salt of a fatty acid derivative as the absorption enhancing component.

The Watts et al. reference discloses a composition comprising: (A) a drug; (B) as an enhancing component, a mixture of a salt of a fatty acid of the type defined in applicants' claims (or said fatty acid) and a particular diglyceride; and (C) a dispersing agent. The heart of the development described in the Watts et al. reference is the use

of the aforementioned mixture of components and the dispersing agent to the drug-containing composition. Watts et al. explain clearly why the aforementioned mixture is required. According to the reference, the use of the fatty acid by itself or the use of the glyceride by itself (each acknowledged as being known to function as an absorption-enhancer) has no acceptable enhancing effect in a mammal, such as a man, except that it is used in a quantity so large as to be a quantity which is too great to be administered (see page 13 beginning at line 24 and continuing to page 14, line 5 of the reference). To formulate the Watts et al. composition, the inventors teach that the composition is in a liquid or semi-solid form (page 8, line 21 of the reference). Accordingly, Watts et al. teach explicitly away from applicants' claimed composition.

It is requested respectfully that the Examiner's §103 rejection be withdrawn.

Miscellaneous

With respect to the amended claims, enclosed herewith is "Version with Markings to Show Changes Made."

A Petition for an extension of time is submitted herewith.

Also submitted herewith are an appointment of Associate Attorney and a request for a change of correspondence address.

Respectfully submitted,
Synnestvedt & Lechner

9/26/01
Date

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Copy With Markings to Show Changes Made

1. (Once Amended). A composition in solid oral dosage form comprising a drug and, as an enhancer, [wherein the enhancer is] a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

4. (Once Amended). The [solid oral dosage form] composition according to claim [2] 1, wherein the enhancer is a sodium salt of a medium chain fatty acid.

39. (Once Amended). A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a therapeutically effective amount of a dose of a composition which is in solid form and which comprises a drug [used] effective in treating the medical condition [together with] and, as an enhancer, a salt of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature [wherein said drug and said enhancer are in the form of the solid oral dosage form of claim 1].

41. (Once Amended) A process for the manufacture of a composition in solid oral dosage form comprising the steps of:

a) providing a blend of [blending] a drug and, as [with] an enhancer, [and optionally additional excipients to form a blend; wherein the enhancer is] a medium chain fatty acid [or an ester, an ether, a] salt having a carbon chain length of from 6 to 20 carbon atoms or a [derivative] salt of a medium chain fatty acid derivative which [is solid at room temperature and] has a carbon chain length of from 6 to 20 carbon atoms and optionally, another constituent(s), wherein each of said drug, enhancer, and optional constituent(s) is a solid at room temperature; [with the provisos that (i) where the enhancer is an ester of a medium chain fatty acid, said chain length of from 6 to 20 carbon atoms relates to the chain length of the carboxylate moiety, and (ii) where the enhancer is an ether of a medium chain fatty acid, at least one alkoxy group has a carbon

chain length of from 6 to 20 carbon atoms;] and

b) forming [a] said solid oral dosage form of the composition from the blend by:
i) direct compression of the blend; [to form the solid oral dosage form,] or
ii) granulating the blend to form a granulate for incorporation into [the] said solid oral dosage form[, or
iii) spray drying the blend to form a multiparticulate for incorporation into the solid oral dosage form].

47. (Once Amended). A composition in solid oral dosage form comprising a drug and, as an enhancer,[wherein the enhancer is] a salt of a derivative of a medium chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms, wherein each of said constituents and any other constituent comprising the composition is a solid at room temperature.

50. (Once Amended). The solid oral dosage form according to claim [50] 49, wherein the capsule is coated with a rate controlling polymer.

52. (New Claim). A dry-blended composition in solid oral dosage form and comprising a drug and, as an enhancer, a salt of a medium-chain fatty acid which has a carbon chain length of from 6 to 20 carbon atoms.